

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
Fort Worth Division**

OUTSOURCING FACILITIES  
ASSOCIATION, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION, et al.,

Defendants.

Civil Action No. 4:24-cv-00953-P

**Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction**

Pursuant to Federal Rule of Civil Procedure 65(a) and (b), Plaintiffs Outsourcing Facilities Association (“OFA”) and North American Custom Laboratories, LLC, doing business as FarmaKeio Custom Compounding (“FarmaKeio”) hereby move the Court to enter (1) a temporary restraining order enjoining the Food and Drug Administration (“FDA”) from taking action against OFA members and FarmaKeio based on their compounding of the drug ingredient Tirzepatide for 14 days while this Court receives briefing and prepares and renders a decision on Plaintiffs’ simultaneously submitted motion for a preliminary injunction, and (2) a preliminary injunction prohibiting the Food and Drug Administration (“FDA”) from taking action against OFA members and FarmaKeio based on their compounding of the drug ingredient Tirzepatide pending final judgment in this case.

For either a temporary restraining order or a preliminary injunction, Plaintiffs “must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest.” *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015) (quoting *Trottie v. Livingston*, 766 F.3d 450, 452 (5th Cir. 2014)). As explained in the attached memorandum of law, Plaintiffs have established

these elements, and preliminary relief is proper to prevent irreparable harm and preserve the status quo until final judgment can be rendered in this case. This Motion is accompanied by a memorandum of law in support and an appendix.

The Court should decline to impose a security requirement under Federal Rule of Civil Procedure 65(c). The amount of security required “is a matter for the discretion of the trial court,” and the Fifth Circuit has held district courts have discretion to “require no security at all.” *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996) (citing *Corrigan Dispatch Company v. Casa Guzman*, 569 F.2d 300, 303 (5th Cir. 1978)). FDA will not suffer financial harm from an injunction that would make a security requirement proper, so no security requirement is appropriate in this case.

Dated: October 8, 2024

/s/ Ty Doyle

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forthcoming

*Attorneys for Plaintiffs*

**Certificate of Service**

I hereby certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on October 8, 2024, and that I caused a copy of the foregoing, and all accompanying papers, to be served via process server and via U.S. mail on the following:

United States Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, Maryland 20903

Dr. Robert M. Califf  
10903 New Hampshire Ave.  
Silver Spring, Maryland 20903

Dated: October 8, 2024

*/s/ Ty Doyle*

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